K050428

JUN 14 2005

Advanced Spinal Technologies, Inc.
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510(k) Summary
Advanced Spinal Mobilization Instrument (ASMI)

Date of Preparation:	February 14, 2005
Submitter:	Advanced Spinal Technologies, Inc. 433 Plaza Real, Suite 255 Boca Raton, Florida 33432
Contact:	Jeffrey R. Perelman, M.D. Phone: (561) 338-9700 Fax: (561) 338-9780 E-Mail: jperelman@advancedspinaltech.com
Specification developer:	Alteristic Instruments Limited 66 Lemon Street Truro, Cornwall TR1 2PN United Kingdom
Contract manufacturer:	SMC Pneumatics (UK) Ltd. Vincent Avenue Crownhill, Milton Keynes MK8 OAN United Kingdom
Trade Name:	Advanced Spinal Mobilization Instrument (ASMI)
Common Name:	Adjusting or Joint Mobilization Instrument
Classification Name:	Plunger-Like Joint Manipulator
Intended Use:	Adjustment, mobilization, or manipulation of the musculoskeletal joints of the spine by a licensed health care professional.
Predicate Devices:	K023462 – Impulse™ Adjusting Instrument K003185 – Full Spectrum Activator® III K021238 – Frye Adjusting Instrument K962239 – Smart Adjuster Adjusting or Joint Mobilization Instrument

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Establishment Registration Number: 3005096823

Regulatory Class: Unclassified

Product Code: LXM

Panel: Physical Medicine

Performance Standards: None known established

Device Description & Specifications:

The Advanced Spinal Mobilization Instrument (ASMI) is a handheld electromechanical instrument used to adjust, mobilize, or manipulate the musculoskeletal joints of the spine. The device is intended for use by a licensed health care professional. Because manual spinal mobilization is difficult to perform, the ASMI gives the licensed health care professional the opportunity to perform spinal mobilization with a handheld electromechanical device.

The device operates in three distinct modes. The introductory mode initiates a therapy session and acclimatizes the patient to the touch and feel of the instrument. The mobilization mode is designed to duplicate the movement and actions of a physical therapist's hands performing spinal mobilization. The recovery mode is used between the mobilization treatments to lightly massage the paraspinal area and promote a soothing feeling of well-being.

The system incorporates a handset connected to a console. The handset consists of a metal body containing four double-acting pistons and two five-port solenoid-operated valves. The console consists of a filter/regulator/filter (FRF) and a metal case which contains a proportional valve and printed circuit board (PCB). The pads, the only patient contact part, are made of silicon rubber. The system is designed for standard connection to a compressed air source.

The equipment is manufactured to the highest possible standards and is failsafe, *i.e.*, if it malfunctions, it simply ceases to operate. The power supply is via a transformer with an output of 1.7 A at 12V. In recovery mode, the ASMI transmits a peak force of 50N. In mobilization mode, the pistons act as air springs or cushions and therefore primarily transmit the mobilizing effort applied by the practitioner.

Substantial Equivalence Comparison:

The Advanced Spinal Mobilization Instrument (ASMI) is substantially equivalent to other FDA listed and 510(k) cleared hand-held chiropractic adjusting/mobilization instruments. Specifically, the ASMI has the same intended use and similar technological characteristics as the above-listed devices. All of these devices are used by licensed professionals to impart or transmit controlled force to musculoskeletal joints as part of the practice of physical therapy, chiropractic medicine, and related professional fields. While substantially equivalent to the identified predicate devices in their totality, the ASMI is similar to, for example, the Impulse

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(K023462) fitted with the dual stylus attachments. The Smart Adjuster (K962239) is also available with a dual prong attachment. Additionally, while all means of activating the impact force are substantially equivalent, the Frye Adjusting Instrument (K021238) is, like the ASMI device, activated pneumatically.

A comparison of the technological characteristics of the current device and the predicate devices is set forth in the chart below.

Comparison Chart:

Feature	ASMI	Impulse	Activator III	Smart Adjuster	Frye
Indicated for adjustment and mobilization of the spine?	Yes	Yes	Yes	Yes	Yes
Hand held adjusting device?	Yes	Yes	Yes	Yes	Yes
Adjustable impact force?	Yes	Yes	Yes	Yes	Yes
Silicone rubber body contact member?	Yes	Yes	Yes	N/A	Yes
Activated pneumatically?	Yes	No	No	N/A	Yes
More than one body contact member available?	Yes	Yes	No	Yes	No

N/A = information not available

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Jeffrey R. Perelman, M.D.
President
Advanced Spinal Technologies, Inc.
433 Plaza Real, Suite 255
Boca Raton, Florida 33432

Re: K050428
Trade/Device Name: Advanced Spinal Mobilization Instrument (ASMI)
Regulatory Class: Unclassified
Product Code: LXM
Dated: June 9, 2005
Received: June 10, 2005

Dear Dr. Perelman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Indications for Use

510(k) Number: K050428

Device Name: Advanced Spinal Mobilization Instrument (ASMI)

Indications for Use: The Advanced Spinal Mobilization Instrument (ASMI) is for adjustment, mobilization, or manipulation of the musculoskeletal joints of the spine by a licensed health care professional. The device is for external use only.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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